UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE PLAVIX® MARKETING, SALES PRACTICE AND PRODUCTS LIABILITY LITIGATION (NO. II)	**MDL DOCKET NO. 2418**
UNITED STATES OF AMERICA, ET AL. V. BRISTOL-MYERS SQUIBB COMPANY, ET AL.	**CASE NO. 3:13-CV-01039-FLW-TJB** **MOTION DAY: DEC. 2, 2013**

MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS RELATOR'S THIRD AMENDED COMPLAINT

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I. INTRODUCTION

Relator acknowledges the uniqueness of the claims asserted in the Third Amended Complaint ("TAC"). Despite Defendants' assertions to the contrary, the fact that the case is novel does not mean that the claims fail. *See Woodruff v. Hamilton Twp. Pub. Sch.*, No. Civ. 06-3815NLH, 2007 WL 1876491, at *5 (D. N.J. June 26, 2007) ("Courts have held, however, that when a claim asserts a novel legal theory of recovery, a court should be reluctant to grant a motion to dismiss because 'novel theories of recovery are best tested for legal sufficiency in light of actual, rather than alleged facts.'" (internal citations omitted)). The False Claims Act ("FCA") was designed to "reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). Relator's claims fall squarely within this confine.

In short, Defendants manipulated clinical trial data to support fraudulent claims regarding Plavix's efficacy relative to cheaper alternatives, such as aspirin. Defendants also induced doctors to write prescriptions for Plavix when it was neither reasonable nor medically necessary. And, Defendants persuaded states and sponsor plans into including Plavix on their formularies when it should not have been. Defendants' intentional scheme caused the federal and state governments to pay for countless prescriptions of Plavix that they would otherwise not have paid. In fact, the federal and state governments paid ***100 times more than necessary***

each time they paid for Plavix when aspirin would have been just as effective. As a result, the United States government and many state governments sustained monumental loss and presently seek to recoup those losses caused by Defendants' violations of the FCA.

II. STANDARD OF REVIEW

In evaluating the sufficiency of the TAC, this Court is "required to accept as true all factual allegations in the complaint and draw all inferences from the facts alleged in the light most favorable to [Relator]." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008). If, "under any reasonable reading of the complaint, [Relator] may be entitled to relief," the motion to dismiss should be denied. *Id*. at 233. "[Relator] is not required to establish the elements of a *prima facie* case but instead, need only put forth allegations that 'raise a reasonable expectation that discovery will reveal evidence of the necessary element.'" *Fowler v. UPMC Shadyside*, 578 F.3d 203, 213 (3d Cir. 2009).

III. ARGUMENT

A. THE TAC STATES A VIABLE CLAIM UNDER THE FALSE CLAIMS ACT.

Under 31 U.S.C. § 3729(a)(1), a person who "knowingly . . . causes to be presented, a false or fraudulent claim for payment or approval . . . is liable to the United States Government for a civil penalty." Similarly, under 31 U.S.C.

§ 3729(a)(2),[1] a person who "knowingly . . . causes to be made or used, a false record or statement material to a false or fraudulent claim . . . is liable to the United States Government for a civil penalty." Relator has plead the required elements for violations under both sections.

Defendants purposefully and knowingly trained their sales force to "confuse"[2] physicians about Plavix, providing and instructing their sales representatives to employ quotes and "sales pitches" that Defendants knew to be wrong, fraudulent, and/or misleading.[3] Because of the wrong and false information provided to the doctors, the doctors prescribed the drug when it was not reasonable and/or medically necessary for their patients and when a dramatically less expensive non-prescription drug, aspirin, provided the same or even better efficacy. The submission of these unreasonable and unnecessary prescriptions to the federal and state governments for reimbursement constituted claims that were statutorily ineligible for payment.

Defendants also defrauded each state's Medicaid program and each Medicare sponsor plan into including Plavix on its formulary by misleading the states and sponsor plans into believing that Plavix was more effective than aspirin for certain indications even though Defendants knew it was not more effective than

[1] Congress amended § 3729(a)(2) in 2009 and re-designated it as § 3729(a)(1)(B). *See* History to 31 U.S.C. § 3729.

[2] Dkt. No. 90 ¶¶ 20-22.

[3] Dkt. No. 90 ¶¶ 20-22.

aspirin.[4] Each time a claim was submitted for payment because Plavix was on a state or sponsor plan's formulary for indications for which Plavix was not more effective than aspirin, and thus deemed "medically necessary" when it was not, it constituted a false claim.[5]

1. Relator Is Not Alleging That Complying With Marketing Regulations Is a Prerequisite to Government Payment.

Relator is not alleging that Defendants' marketing techniques, in and of themselves, constitute false claims. Relator is alleging that Defendants purposefully marketed Plavix to physicians and to state and sponsor plan formulary committees in order to have claims submitted for payment that did not comply with the federal and state regulations that did not meet conditions for payment – specifically, that the drug was either "reasonable and necessary" or "medically necessary."[6] Thus, Defendants' marketing practices "knowingly cause[d] to be presented, a false or fraudulent claim for approval," 31 U.S.C. § 3729(a)(1), and "knowingly cause[d] to be made, a false record of statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(2).

Wilkins is not "directly on point." In *Wilkins*, the court explained that courts have distinguished between regulations that are conditions of *participation* in federally funded programs and those that are conditions of Government *payment*.

[4] Dkt. No. 90 ¶¶ 129-93.
[5] Dkt. No. 90 ¶¶ 129-93.
[6] *See* Dkt. No 90 ¶¶ 42, 49.

United States ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 310 (3d Cir. 2011). Based on that distinction, the court found plaintiff's claim for relief conditioned on compliance with marketing regulations, which was merely a condition for participation but not for payment, to be insufficient. *Id.* The language cited by Defendants is not on point: the allegations at issue here are related to a condition *for payment*, not participation.[7] Interestingly, *Wilkins* is on point for the purpose of establishing that Relator's claims are permissible on their face – Relator claims that compliance with the regulation Defendants violated was a condition of payment from the Government. *See id.* at 309 ("[T]o plead a claim upon which relief could be granted under a false certification theory, either express or implied, a plaintiff must show that compliance with the regulation which the defendant allegedly violated was a condition of payment from the Government.").

Defendants' other cited cases are similarly irrelevant. *See United States ex rel. Simpson v. Bayer Corp.*, Civ. Action No. 05-3895 JLL, 2013 WL 4710587, at *9 (D. N.J. Aug. 30, 2013) (determining that misbranding allegations were not sufficiently connected to false claims *for payment*); *United States ex rel. Ge v. Takeda Pharm. Co. Ltd.*, Civ. Action No. 10-11043-FDS, 2012 WL 5398564, at *6 (D. Mass. Nov. 1, 2012) (discussing adverse-event reporting requirements, not the "reasonable and necessary" or "medically necessary" standard for reimbursement).

[7] Dkt. No. 90 ¶¶ 24, 26, 42, 45-46, 49-51, 197, 199.

Again, Relator is not alleging that Defendants' marketing techniques, in and of themselves, constitute false claims. Thus, *Simpson* and *Ge* are inapposite.

2. Medicare Part D Requires That Drugs Be "Reasonable And Necessary" In Order To Be Covered, And Defendants' Misrepresentations Caused Physicians To Write Prescriptions For Plavix When The Drug Did Not Comply With That Regulation.

The Medicare statute explicitly permits plans to refuse to pay for drugs unless they are both "covered Part D drugs" *and* reasonable and necessary. "Centers for Medicare and Medicaid Services instructs physicians that 'Part D drugs *must* be prescribed' in accordance with the 'reasonable and necessary' standard."[8] Medicare Part D plan sponsors have utilized this statute to limit reimbursement of prescription drugs,[9] creating requirements that the drug not only be a covered outpatient drug, but also be "medically necessary, meaning reasonable and necessary."[10] Defendants' argument that there is not a "reasonable and necessary" precondition of payment "for Medicare Part D reimbursements of on-label prescriptions,"[11] while audacious, is simply incorrect.

Defendants' misrepresentations prevented physicians from having the opportunity to "make considered medical judgments." *Strom ex rel. United States v. Scios, Inc.*, 676 F. Supp. 2d 884, 895 n.2 (N.D. Cal. 2009). Defendants'

[8] Dkt. No. 90 ¶ 44.
[9] Dkt. No. 90 ¶ 45.
[10] Dkt. No. 90 ¶ 45.
[11] Dkt. No. 94-1, at 10.

misrepresentations "left many physicians with the false impression that Plavix was essentially the *only option* for effective patient care in a host of contexts,"[12] thereby causing physicians to write prescriptions for Plavix even when the drug was not reasonable and necessary given a far less expensive, safer, and more effective option, like aspirin. "[A] prescription . . . in a context where it is not 'reasonable' or 'necessary' would be statutorily ineligible for reimbursement," and therefore, constitutes a false claim. *Id*. at 891.

Defendants' alternative argument that prescriptions of Plavix satisfy the "reasonable and necessary" standard[13] is also incorrect. Just because a drug is "FDA-approved" does not mean that it is "reasonable and necessary." *See, e.g.*, *Almy v. Sebelius*, 749 F. Supp. 2d 315, 330 (D. Md. 2010) (explaining that FDA clearance or approval does not automatically guarantee Medicare coverage, noting "the FDA and the CMS are independent entities with different agendas and statutory mandates"). Here, Defendants' conduct caused physicians to prescribe Plavix when it was not reasonable and necessary, given that there was a non-prescription drug (aspirin) that was at least as effective – if not more effective – than Plavix at 1/100 of the cost of Plavix. Regardless, whether or not Plavix was "reasonable and necessary" is a factual dispute, and therefore not a proper basis upon which a motion to dismiss should be granted.

[12] Dkt. No. 90 ¶ 195 (emphasis added).
[13] Dkt. No. 94-1, at 10

Defendants caused physicians and pharmacists to submit prescriptions of Plavix for payment, thereby certifying that they were "reasonable and necessary," a condition for payment under Medicare Part D, when the prescriptions were not "reasonable and necessary" given the fraudulently withheld information about Plavix's efficacy. These are false claims.

3. Medicaid Requires That Drugs Be "Medically Necessary" In Order To Be Covered, And Defendants' Misrepresentations Caused Physicians To Write Prescriptions For Plavix When They Did Not Comply With That Regulation.

Defendants' Medicaid arguments are insupportable. Without authority, they state that "Medicaid ***mandates*** reimbursement of covered outpatient drugs . . . ."[14] This is not true. The requirement that a drug be a "covered outpatient drug" is just one prerequisite to payment coverage. "Once services are covered, the next issue is whether the covered service is medically necessary." *Hunter v. Chiles*, 944 F. Supp. 914, 921 (S.D. Fla. 1996). This is because the federal government authorizes state Medicaid agencies to "place appropriate limits on a service based on such criteria as medical necessity." 42 C.F.R. § 440.230(d); *Hunter*, 944 F. Supp. at 921. All states have done so.[15]

[14] Dkt. No. 94-1, at 7.
[15] Dkt. No. 90 ¶¶ 52-102.

South Carolina's Medicaid agency, for example, "pays for prescribed drugs when covered *and* medically necessary."[16] Kansas's Medicaid agency will not "reimburse a provider for pharmacy series unless the service was medically necessary," which contemplates that the service be "cost-effective."[17] New Mexico's Medicaid agency reimburses providers for furnishing covered services to Medicaid recipients only when the services are "medically necessary."[18] Massachusetts's Medicaid program "will not pay a provider for services that are not medically necessary and may impose sanctions on a provider for . . . prescribing a service . . . where such service . . . is not medically necessary."[19] Arizona's regulations define "pharmaceutical services" to include only "medically necessary medications that are prescribed by a physician."[20] In Montana, prescribed drugs "may only be those that are medically necessary and that are the most efficient and cost-effective."[21] The list goes on.[22]

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[16] Dkt. No. 90 ¶ 92 (emphasis added) (citing S.C. Health & Human Servs., S.C. Healthy Connections (Medicaid) Provider Manual, Pharmacy Servs. (Feb. 1, 2005, updated Mar. 1., 2003) § 1, at 1-10; S.C. Code Ann. Regs. 126-301).

[17] Dkt. No. 90 ¶ 68 (citing Kan. Admin. Regs. §§ 30-5-63; 30-5-92(a)).

[18] Dkt. No. 90 ¶ 83 (citing N.M. Admin. Code §§ 8.300.1.9; 8.302.5.10; 8.301.2.9).

[19] Dkt. No. 90 ¶ 73 (citing 130 Mass. Code Regs. 450.204; 450.101).

[20] Dkt. No. 90 ¶ 54 (citing Ariz. Admin. Code § R9-22-201).

[21] Dkt. No. 90 ¶ 78 (citing Mont. Code Ann. § 53-6-101(9); 53-6-101(4)(h)).

[22] *See* Dkt. No. 90 ¶ 52 (explaining Alabama's "medically necessary" requirement); ¶ 53 (same, for Alaska); ¶ 55 (same, for Arkansas); ¶ 56 (same, for California); ¶ 57 (same, for Colorado); ¶ 58 (same, for Connecticut); ¶ 59 (same,

Whether a prescription drug is medically necessary is decided in the first instance by the treating physician. *See Smith v. Rasmussen*, 249 F.3d 755, 759 (8th Cir. 2001) ("[T]he Medicaid statute and regulatory scheme create a presumption in favor of the medical judgment of the attending physician in determining the medical necessity of treatment." (quoting *Weaver v. Reagen*, 886 F.2d 194, 200 (8th Cir. 1989)). Defendants' misrepresentations about the efficacy of Plavix as compared to aspirin deprived physicians of the opportunity to make this decision based on accurate information.[23] The result: Defendants caused countless physicians to prescribe Plavix when Plavix was not "medically necessary," and therefore, not covered by Medicaid.[24] The resulting Medicaid claims are false claims. *See United States v. Kensington Hosp.*, 760 F. Supp. 1120, 1127 (E.D. Pa. 1991) ("Payment for services [including prescription drugs] not medically

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for Delaware); ¶ 60 (same, for the District of Columbia); ¶ 61 (same, for Florida); ¶ 62 (same, for Georgia); ¶ 63 (same, for Hawaii); ¶ 64 (same, for Idaho); ¶ 65 (same, for Illinois); ¶ 66 (same, for Indiana); ¶ 67 (same, for Iowa); ¶ 69 (same, for Kentucky); ¶ 70 (same, for Louisiana); ¶ 71 (same, for Maine); ¶ 72 (same, for Maryland); ¶ 74 (same, for Michigan); ¶ 75 (same, for Minnesota); ¶ 76 (same, for Mississippi); ¶ 77 (same, for Missouri); ¶ 79 (same, for Nebraska); ¶ 80 (same, for Nevada); ¶ 81 (same, for New Hampshire); ¶ 82 (same, for New Jersey); ¶ 84 (same, for New York); ¶ 85 (same, for North Carolina); ¶ 86 (same, for North Dakota); ¶ 87 (same, for Ohio); ¶ 88 (same, for Oklahoma); ¶ 89 (same, for Oregon); ¶ 90 (same, for Pennsylvania); ¶ 91 (same, for Rhode Island); ¶ 93 (same, for South Dakota); ¶ 94 (same, for Tennessee); ¶ 95 (same, for Texas); ¶ 96 (same, for Utah); ¶ 97 (same, for Vermont); ¶ 98 (same, for Virginia); ¶ 99 (same, for Washington); ¶ 100 (same, for West Virginia); ¶ 101 (same, for Wisconsin); ¶ 102 (same, for Wyoming).

[23] Dkt. No. 90 ¶ 103.

[24] Dkt. No. 90 ¶ 103-04.

necessary clearly constitutes an injury to the government sufficient to withstand a motion to dismiss."); *see also Strom*, 676 F. Supp. 2d at 891 (holding that a prescription for a drug not meeting the underlying qualifications for federal reimbursement constitutes a false claim).

Defendants cite *Edmonds* for the proposition that imposing a "medically necessary" precondition to payment "would violate federal law."[25] The case does not so hold. *See Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1326 (S.D. Fla. 2006). In *Edmonds*, the plaintiffs were Medicaid recipients challenging a policy in Florida where reimbursement was denied except for four indications. *Id*. at 1325. The drug was "safe and inexpensive" and "*medically necessary* for the treatment of their conditions." *Id*. (emphasis added). The opinion related to whether or not the state could exclude the drug from coverage on the basis that its prescribed use was not for a "medically accepted indication." *Id.* at 1327. The court found the state's policy problematic in part because the state retained the final authority over coverage for non-formulary drugs, instead of the prescribing doctor. *Id.* at 1330. The court found the state's Medicaid program's "determination that most of the off-label uses cited in DRUGDEX are not 'medically accepted indications' because they are not substantiated by double-blind, placebo-controlled, randomized clinical trials [to be] erroneous." *Id*. at 1336. Because of this reason,

[25] Dkt. No. 94-1, at 9.

the court determined that the state's application of its policy "which stems from this erroneous interpretation, violates federal law." *Id*.

Medicaid places a "medical necessity" standard for reimbursement for prescription drugs.[26] Defendants' conduct caused countless prescriptions for Plavix to be submitted to the Government for reimbursement when they were not medically necessary given the availability of a cheaper alternative – aspirin. As such, Defendants violated the FCA.

4. Defendants Induced Each State's Medicaid Program And Each Medicare Sponsor Plan Into Including Plavix On Its Formulary When It Should Not Have Been.

Federal law provides that states may establish a formulary to exclude outpatient drugs if the drug "does not have a significant clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary."[27] Thus, states may categorically exclude on-label outpatient drugs

> if the drug does not have a meaningful advantage in terms of effectiveness, and may exclude in this manner to achieve program savings. Importantly, the statute requires the formulary committee to consist of 'physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State.' Thus, the persons that constitute these committees are the very same persons that [Defendants] targeted with their false marketing – physicians and pharmacists.[28]

[26] Dkt. No. 90 ¶¶ 52-102.
[27] Dkt. No. 90 ¶ 129 (citing 42 U.S.C. § 1396r-8(d)(4)(C)).
[28] Dkt. No. 90 ¶ 130-31.

In the TAC, Relator describes the formulary process in each and every state,[29] and further pleads that each state's Medicaid program would have excluded Plavix from its Medicaid formulary but for the false marketing scheme perpetrated by Defendants to mislead the states into believing that Plavix was more effective

[29] *See* Dkt. No. 90 ¶ 133 (describing Alabama's process); ¶ 134 (describing Alaska's process); ¶ 135 (describing Arizona's process; ¶ 136 (describing Arkansas's process); ¶ 137 (describing California's process); ¶ 138 (describing Colorado's process); ¶ 139 (describing Connecticut's process); ¶ 140 (describing Delaware's process); ¶ 141 (describing the District of Columbia's process); ¶ 142 (describing Florida's process); ¶ 143 (describing Georgia's process); ¶ 144 (describing Hawaii's process); ¶ 145 (describing Idaho's process); ¶ 146 (describing Illinois's process); ¶ 147 (describing Indiana's process); ¶ 148 (describing Iowa's process); ¶ 149 (describing Kansas's process); ¶ 150 (describing Kentucky's process); ¶ 151 (describing Louisiana's process); ¶ 152 (describing Maine's process); ¶ 153 (describing Maryland's process); ¶ 154 (describing Massachusetts' process); ¶ 155 (describing Michigan's process); ¶ 156 (describing Minnesota's process); ¶ 157 (describing Mississippi's process); ¶ 158 (describing Missouri's process); ¶ 159 (describing Montana's process); ¶ 160 (describing Nebraska's process); ¶ 161 (describing Nevada's process); ¶ 162 (describing New Hampshire's process); ¶ 163 (describing New Jersey's process); ¶ 164 (describing New Mexico's process); ¶ 165 (describing New York's process); ¶ 166 (describing North Carolina's process); ¶ 167 (describing North Dakota's process); ¶ 168 (describing Ohio's process); ¶ 169 (describing Oklahoma's process); ¶ 170 (describing Oregon's process); ¶ 171 (describing Pennsylvania's process); ¶ 172 (describing Rhode Island's process); ¶ 173 (describing South Carolina's process); ¶ 174 (describing South Dakota's process); ¶ 175 (describing Tennessee's process); ¶ 176 (describing Texas's process); ¶ 177 (describing Utah's process); ¶ 178 (describing Vermont's process); ¶ 179 (describing Virginia's process); ¶ 180 (describing Washington's process); ¶ 181 (describing West Virginia's process); ¶ 182 (describing Wisconsin's process); ¶ 183 (describing Wyoming's process).

than aspirin for certain indications even though it was not. The same is true of the Medicare plan sponsors.[30]

In other words, Congress allowed states and plan sponsors to *exclude from coverage* prescription drugs that are not clinically more effective than other drugs, and allows such an exclusion to "achieve program savings."[31] Defendants duped the states and plan sponsors into believing that Plavix was more effective than far less expensive alternatives in order to be placed on these formularies. Defendants' complaint that Relator's allegations are speculative ignores the reality that the Pharmacy and Therapeutics Committees ("P&T Committees") are comprised of doctors and pharmacists[32] – the very individuals targeted by Defendants in their scheme. Thus, Relator's facts about how Defendants misled the doctors and pharmacists[33] are equally applicable in this context. Physicians and pharmacists made a "clinical decision," but did so under the influence of Defendants' false marketing scheme.

As Relator explains in the TAC, "[Defendants'] scheme to defraud caused states to include Plavix on their state's Medicaid formularies for indications for which Plavix is not medically necessary."[34] Therefore, each time a prescription for

[30] Dkt. No. 90 ¶¶ 188-193.
[31] Dkt. No. 90 ¶130.
[32] Dkt. No. 90 ¶ 131.
[33] *See, e.g.*, Dkt. No. 90 ¶¶ 20-22.
[34] Dkt. No. 90 ¶ 24.

Plavix was reimbursed because of its status on the formulary, and thus deemed "medically necessary" by the Medicare or Medicaid program, even though it was not actually "medically necessary," that prescription was a false claim against the government.

B. RELATOR'S CLAIMS SATISFY RULE 9(B)'S SPECIFICITY REQUIREMENTS.

The Third Circuit has recognized that with respect to Rule 9(b), "focusing exclusively on the particularity requirement is 'too narrow an approach and fails to take account of the general simplicity and flexibility contemplated by the rules.'" *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1989) (quoting *Christidis v. First Pa. Mortgage Trust*, 717 F.2d 96, 99 (3d Cir. 1983)). Specifically, courts "must be sensitive to the fact that application of Rule 9(b) prior to discovery 'may permit sophisticated defrauders to successfully conceal the details of their fraud." *Id.* For that reason, "Rule 9(b) is generally considered satisfied when a defendant has 'fair notice' of the charges against it." *United States ex rel. Budike v. PECO Energy*, 897 F. Supp. 2d 300, 316 (E.D. Pa. 2012).

Defendants cite to two personal injury cases for alleged support that Relator does not provide sufficient specificity. Yet, FCA cases are their own creature, and completely distinct from what is required where a single plaintiff brings a personal injury claim against a defendant. Defendants also criticize the TAC for failure to

allege "a single doctor that prescribed" Plavix or "even one false claim."[35] However, in *Wilkins*, an FCA case heavily relied upon by Defendants, the Third Circuit stated: "to our knowledge we never have held that a plaintiff must identify a specific claim for payment at the *pleading stage* of the case to state a claim for relief." *Wilkins*, 659 F.3d at 308. Indeed, "requiring every relator alleging the indirect submission of fraudulent claims to identify in his complaint a specific false claim would effectively eliminate part of the False Claims Act." *United States ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 679 (E.D. Pa. 2010).

Relator alleges an extensive scheme by Defendants to defraud the government that has been ongoing since 1996. The TAC details the who, what, when, where, and how of the fraudulent scheme, thereby satisfying Rule 9(b).[36]

1. Relator Alleges "The Who."

The TAC specifically names each perpetrator of the fraud: Bristol Myers Squibb, Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc.[37] In addition, with Relator as a specific example, the TAC alleges that *members of the sales force* were instructed by Defendants to promote Plavix as

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[35] Dkt. No. 94-1, at 14-15.

[36] It should be noted that Defendants did not move for reconsideration of Judge Herndon's opinion on the basis of their Rule 9(b) argument. Judge Herndon rejected Defendants' argument in his opinion, determining that "Relator's instant allegations are sufficient to comport with the requirements of Rule 9(b) in this instance," because "Relator states with adequate particularity the circumstances of defendant's fraudulent scheme." Mem. & Order at 8, Jan. 30, 2013 ("**Exhibit A**").

[37] Dkt. No. 90 ¶¶ 3, 15, 19-23, 38-41, 114-212.

having certain characteristics known by Defendants to be untrue, which thereby resulted in false claims.[38] For instance, Defendants instructed their sales force, including Relator, to promote Plavix as being superior to aspirin for certain indicated uses, when it was not.[39] The TAC sufficiently sets forth the parties involved in the FCA violations, thereby fulfilling the "who" prong of the specificity requirements.

2. Relator Alleges "The What" And "The How."

The TAC alleges that Defendants: (1) wrongfully promoted Plavix, through their sales representatives (including Relator), to physicians, as superior to aspirin for patients who had recently suffered strokes or myocardial infarctions; (2) misrepresented to physicians, through their sales representatives (including Relator), that Aggrenox was inferior to Plavix; (3) targeted physicians and pharmacists who make prescribing decisions and who are statutorily required to make up the P&T committees that make decisions about Medicare and Medicaid formularies; and (4) caused physicians to submit false claims to the government.[40] Relator pleads precisely *what* fraudulent scheme is made the basis of the wrongdoing and just *how* the fraudulent scheme was conducted. This satisfies

[38] Dkt. No. 90 ¶¶ 19-21, 119, 128.
[39] Dkt. No. 90 ¶¶ 19-20, 119, 122.
[40] Dkt. No. 90 ¶¶ 3, 19-23, 114-212.

Rule 9(b)'s pleading requirement. Defendants' fraudulent scheme, as alleged by Relator in the TAC, is more fully detailed below.

a. Defendants Fraudulently Promoted Plavix As Superior To Aspirin.

As described in the TAC, Defendants well knew that their claims that Plavix was superior to aspirin were false; nevertheless, they promoted Plavix as such.[41] The 1996 CAPRIE study, for example, "demonstrated [in the recent stroke and recent myocardial infarction subgroups] that there was no statistically significant reduction in the primary endpoint for patients taking Plavix as compared to patients taking aspirin."[42] And, in 2001, the FDA's Division of Drug Marketing and Communications ("DDMAC") sent Defendants a letter stating that their promotions were misleading as they "suggest [] that Plavix is superior to aspirin when such has not been demonstrated by substantial evidence."[43] Instead of properly informing health care professionals and revealing this information, Defendants manipulated clinical trial data to support their false claims regarding Plavix's characteristics. For instance:

- "On [Defendants'] pamphlets provided to physicians summarizing the CAPRIE study, the subgroup analysis [demonstrating that Plavix was not superior to aspirin] was not provided."[44]

[41] Dkt. No. 90 ¶¶ 3, 8-12, 19-20, 114-212.
[42] Dkt. No. 90 ¶ 117.
[43] Dkt. No. 90 ¶¶ 8-12.
[44] Dkt. No. 90 ¶ 117.

- "[C]ompany sales pamphlets (citing CAPRIE) claimed that there was 'proven efficacy' of Plavix over aspirin in ischemic stroke patients[,]"[45] which was false.

- "[Defendants] ordered its sales personnel to promote Plavix as being superior to aspirin in stroke patients[, which was false]. As a result, Plavix was regularly and systematically presented to physicians as superior to aspirin for treatment of stroke patients."[46]

- "[Defendants] also misled physicians regarding the efficacy of Plavix plus aspirin dual therapy following coronary artery bypass grafting ("CABG"). Upon information and belief, [Defendants] obtained a label change for Plavix based on [the CURE trial] to indicate that Plavix was effective for treatment post-CABG. However, . . . [n]o benefit was seen for [Plavix] use after CABG in the CURE trial."[47]

- "[Defendants] ordered its sales force to promote Plavix as comparably safe to aspirin based on the CAPRIE study even though the CAPRIE study compared Plavix to a more toxic dose of aspirin that is not regularly prescribed today."[48]

- "The results of the Chan Study were not disclosed [by Defendants] to prescribing neurologists."[49]

b. Defendants Misrepresented That Aggrenox Was Inferior To Plavix.

The PRoFESS study "'showed no difference in stroke recurrence among patients assigned to [Plavix] compared with patients assigned to [Aggrenox],'" and

[45] Dkt. No. 90 ¶ 118.
[46] Dkt. No. 90 ¶ 119.
[47] Dkt. No. 90 ¶ 121 (reference added).
[48] Dkt. No. 90 ¶ 122.
[49] Dkt. No. 90 ¶ 123. The TAC is not confined to these general allegations, but also details Relator's personal experience in the TAC and her attached affidavit, which includes being "instructed by Sanofi" to "regularly promote[] Plavix [as] having certain characteristics that BMS/Sanofi knew were not true." Dkt. No. 90 ¶¶ 19-20; *see also* Dkt. No. 90-1 ¶¶ 18-19, 22.

"[t]here was also no statistically significant difference between the two drugs in causing major hemorrhagic events."[50] Despite this fact, Defendants instructed their sales force, including Relator, to present the PRoFESS data in a manner designed to confuse and mislead physicians into believing that Aggrenox was inferior to Plavix.[51] That is, they instructed their sales force to emphasize that "it should not be concluded from the study that Aggrenox has similar efficacy and safety to Plavix in stroke patients."[52] Such statements were designed to be and are intentionally misleading.

c. Physicians And Pharmacists Make Up The P&T Committees.

Importantly, federal law requires that the formulary committee in each state consist of "physicians, pharmacists, and other appropriate individuals . . . Thus, the persons that constitute these committees are the very same persons that [Defendants] targeted with their false marketing."[53] Defendants purposefully targeted these individuals in part to keep Plavix on state and sponsor plan formularies, even though it should not have been.

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[50] Dkt. No. 90 ¶ 127.

[51] Dkt. No. 90 ¶¶ 21, 126-28.

[52] Dkt. No. 90 ¶¶ 21, 128. Again, the TAC also details Relator's own personal experience related to this portion of Defendants' fraudulent scheme. Dkt. No. 90 ¶ 21; *see also* Dkt. No. 90-1 ¶¶ 29, 31.

[53] Dkt. No. 90 ¶ 131.

d. Defendants' Conduct Caused False Claims To Be Submitted.

Defendants argue that Relator has not shown that Defendants' conduct *caused* false claims to be submitted. They are wrong. As an integral part of their fraudulent scheme, Defendants "targeted doctors whose patients rely on Government Payors for health care treatment so as to wrongfully inflate sales and profits at a tremendous cost to American taxpayers."[54] The purpose of targeting such doctors was based on their belief that these "physicians' inherent willingness to prescribe more expensive drugs to patients who relied on government assistance in obtaining prescription medication."[55] Defendants also targeted physicians and pharmacists in order to influence decisions about state and sponsor plan formularies.[56] By misrepresenting Plavix's efficacy, Defendants convinced physicians of Plavix's false superiority and left them with the mistaken impression that Plavix was the only option.[57] These actions resulted in physicians submitting false claims to the government.[58] Specifically, "[Defendants'] scheme caused physicians and pharmacists to submit claims for reimbursement that constituted false claims because Plavix was not 'reasonable and necessary' even though that

[54] Dkt. No. 90 ¶¶ 22-23; *see also* Dkt. No. 90-1 ¶ 32.
[55] Dkt. No. 90 ¶¶ 22, 194; *see also* Dkt. No. 90-1 ¶ 33.
[56] *See* Dkt. No. 90 ¶¶ 129-87.
[57] Dkt. No. 90 ¶ 195; *see also* Dkt. No. 90-1 ¶¶ 36-37.
[58] Dkt. No. 90 ¶¶ 196, 208, 209; *see also* Dkt. No. 90-1 ¶ 38.

was a prerequisite for payment."[59] Additionally, "states may [categorically] exclude even on-label outpatient drugs if the drug does not have a meaningful advantage in terms of effectiveness, and may exclude in this manner to achieve program savings."[60] Defendants "falsely marketed Plavix in order to trick states [and sponsor plans] into including Plavix on their formulary when they otherwise would not have done so, considering aspirin is just as effective and extraordinarily cheaper."[61] Each time a prescription was reimbursed on the basis of it being on a state or sponsor plan formulary, Defendants assuredly *caused* the submission of a false claim.

3. Relator Alleges "The When."

In the TAC, Relator states that since 1996, when the CAPRIE study was published, Defendants have falsely promoted Plavix as superior to aspirin.[62] Defendants engaged in such promotion, through their sales force and materials provided to physicians, despite the fact that the CAPRIE study did not support such a claim. Defendants continue to do so today.[63]

Further, Relator details specific dates on which Defendants knew of the falsity of their Plavix assertions. For instance: (1) the 2001 DDMAC letter sent to

[59] Dkt. No. 90 ¶ 197.
[60] Dkt. No. 90 ¶ 130.
[61] Dkt. No. 90 ¶ 184.
[62] Dkt. No. 90 ¶¶ 38, 115-21, 123.
[63] *See* Dkt. No. 90 ¶¶ 20, 115-21, 123.

Defendants stating that Defendants' "sales aid overstated the efficacy of Plavix, made unsubstantiated superiority claims, constituted a misleading efficacy presentation, and lacked fair balance";[64] (2) the January 20, 2005 Chan Study showing that Plavix caused "significantly more gastrointestinal bleeding";[65] and (3) the 2008 study negating Plavix's alleged inferiority to Aggrenox (aspirin + dipyridamole).[66] Nevertheless, Defendants continued their illegal and deceptive promotion of Plavix.

Finally, Relator provides the specific time frames in which she, herself, was personally involved in Defendants' fraudulent scheme. Relator began working for BMS in 1999 and assumed a sales position with Sanofi in 2003.[67] Relator received training for the marketing of Plavix beginning in 2003.[68] During the course of her employment with Defendants, Relator was instructed to promote Plavix as having certain characteristics that Defendants knew were untrue, to misrepresent and withhold information and certain studies, and to target physicians who wrote significant numbers of prescriptions for patients covered by Government Payors.[69]

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[64] Dkt. No. 90 ¶¶ 8-12.

[65] Dkt. No. 90 ¶¶ 20, 122-23. Additional studies in 2011 and early 2012 indicated that Plavix may pose a greater bleeding risk than aspirin, yet Defendants have not altered their promotional materials to reflect such conclusions. Dkt. No. 90 ¶¶ 124-125.

[66] Dkt. No. 90 ¶¶ 21, 126-28.

[67] Dkt. No. 90 ¶ 16; *see also* Dkt. No. 90-1 ¶¶ 3-6.

[68] Dkt. No. 90 ¶ 17; *see also* Dkt. No. 90-1 ¶ 6.

[69] Dkt. No. 90 ¶¶ 19-22; *see also* Dkt. No. 90-1 ¶¶ 18-19, 22, 29, 31-38.

As courts in this Circuit have held, when the alleged conduct occurs over a long period of time, the complaint must only specify a general time frame during which the fraud occurred. *United States ex rel. Hunt v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430, 437 (E.D. Pa. 2004); *see also Budike*, 897 F.Supp.2d at 318. ("Although Relator does not provide many specific dates in the Amended Complaint, he adequately alleges 'when' the FCA violations occurred. These violations occurred from September 4, 2003 to 2007."). Relator does this and more. Here, Relator alleges that since 1996, Defendants have knowingly presented physicians with false information regarding the efficacy of Plavix compared to far less expensive alternatives such as aspirin and have manipulated, misrepresented, and/or withheld medically important clinical data from physicians in order to convince physicians to prescribe Plavix.

4. Relator Alleges "The Where."

Relator alleges that Defendants co-marketed Plavix in the United States.[70] Further, Relator makes clear the place at issue is anywhere in the United States where Defendants marketed and sold the drug Plavix. More specifically, Relator lists several representative examples of locations where the false claims occurred. For instance, Relator brings claims on behalf of Illinois, California, Delaware, District of Columbia, Florida, Hawaii, Nevada, Tennessee, Texas, Virginia,

[70] Dkt. No. 90 ¶¶ 1, 37.

Georgia, Indiana, Michigan, Montana, New Mexico, New York, Massachusetts, City of Chicago, New Jersey, Rhode Island, Wisconsin, Oklahoma, North Carolina, Minnesota, Colorado, and Connecticut.[71] Moreover, Relator's affidavit clearly specifies that Relator was trained and instructed by Defendants regarding Plavix in St. Louis and Dallas.[72] Identifying the state and/or city where Defendants' conduct occurred is sufficient to satisfy the standards of Rule 9(b). *See United States ex rel. Estrada v. Quad City Prosthetic, Inc.*, No. 06-4015, 2011 WL 3273142, at *5 (C.D. Ill. Aug. 1, 2011).

* * *

Relator has sufficiently alleged the "who, what, when, where, and how" of the circumstances constituting fraud. Defendants' motion to dismiss for failure to comply with Rule 9(b) should be denied. *See United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 602 (E.D. Pa. 2012) ("Defendants cannot argue that they are unaware of the precise 'misconduct with which they are charged.'").

C. RELATOR IS THE ORIGINAL SOURCE OF UNIQUE ALLEGATIONS THAT ARE NOT BASED UPON OR SUBSTANTIALLY THE SAME AS PUBLIC DISCLOSURES.

In considering Defendants' motion to dismiss the Second Amended Complaint, Judge Herndon rejected this exact argument in his opinion, determining

[71] Dkt. No. 90 ¶¶ 105, 220-455.
[72] Dkt. No. 90-1 ¶ 6; *see also* Dkt. No. 90 ¶ 18.

that because Defendants asked the court to consider documents outside the pleadings, the record was not adequate to make "such a factual determination at this stage in the proceedings . . . [Judge Herndon thus] decline[d] to do so."[73] As this motion sits in the same posture, Relator respectfully requests that this Court also decline to consider the documents outside of the pleadings that Defendants use as a basis for an argument about subject matter jurisdiction.[74]

In the event that this Court considers the argument, Relator's claims are precisely what the False Claims Act encourages—lawsuits by relators who have firsthand knowledge of fraud against the government. *United States ex rel. Atkinson v. PA. Shipbuilding Co.*, 473 F.3d 506, 519-520 (3d Cir. 2007). As a member of Defendants' sales force for almost a decade, Relator witnessed firsthand an ongoing plan to defraud the government by misleading physicians into prescribing Plavix even though the drug was no more effective than a much less expensive and safer aspirin.[75] Defendants conducted their plan by training, instructing, and directing their sales representatives (including Relator) to "confuse"[76] physicians and to "focus sales calls on physicians and prescribers

[73] Exhibit A, at 7.

[74] Again, it should be noted that Defendants did not move for reconsideration of Judge Herndon's opinion on the basis of their public disclosure argument.

[75] *See, e.g.*, Dkt. No. 90 ¶¶ 110-111.

[76] *See, e.g.*, Dkt. No. 90 ¶ 21.

whose patients relied on"[77] Medicaid and Medicare—doctors with "an inherent willingness to prescribe more expensive drugs."[78] This information—which underlies Relator's claim—was not publicly disclosed prior to this lawsuit, and Relator is an original source of this information. Accordingly, this Court should deny Defendants' motion to dismiss.

1. Relator Has Direct And Independent Knowledge Of The Facts Of Defendants' Fraudulent Conduct.

Even if this Court finds that Relator's claims were "based upon" or "substantially similar as" public disclosures (which they are not, as described below), the public disclosure bar should not apply because Relator is an "original source" of the information. *See United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 332 (3d Cir. 2005) (referring to the original source exception as a "savings clause" that preserves suits brought by an original source of the information, even where there have been prior public disclosures).

Indeed, the Supreme Court has implied that the main jurisdictional focus is on the "original source" requirement. *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 471-72 (2007). An "original source" is "an individual who has direct and independent knowledge of the information on which the allegations are

[77] Dkt. No. 90 ¶ 22.
[78] Dkt. No. 90 ¶ 110.

based."[79] 31 U.S.C. § 3730(e)(4) (pre-PPACA).[80] "Direct knowledge is knowledge obtained without any intervening agency, instrumentality or influence: immediate." *Atkinson*, 473 F.3d at 520 (internal quotation marks and citation omitted)). Direct knowledge can be derived from personal involvement in the fraudulent activity. *Id*. To establish "independent" knowledge, courts require that that the relator's knowledge not depend on public disclosures. *Id.* Relator meets this standard.

The heart of Relator's allegations is that Defendants knowingly coached and instructed their sales representatives to provide false information to physicians and to intentionally persuade and cause physicians to submit unreasonable and

[79] The statute also requires that a relator voluntarily provide the information to the government, and Relator's fulfillment of this requirement is not disputed. To be clear, Relator disclosed her allegations to the government before filing suit.

[80] As a part of PPACA, Congress also amended the "original source" exception. Under the current statute, "'original source' means an individual . . . who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under [the FCA]." 31 U.S.C. § 3730(e)(4)(B) (post-PPACA). Relator qualifies as an original source under this standard as well because Relator was the first person to inform the government that Defendants affirmatively knew the truth about Plavix, disregarded that truth, and engaged in a fraudulent scheme to use its sales force to dupe doctors into prescribing Plavix. *Cf. United States ex rel. Osheroff v. Humana, Inc.*, No. 10-24486-cv-SCOLA, 2012 WL 4479072, at *12 (S.D. Fla. Sept. 28, 2012) (determining that the relator was not an original source because the independent knowledge was relevant to the defendants' anticipated affirmative defenses, but not to the relator's actual claims).

unnecessary prescriptions for Plavix which constituted false claims against the government. Specifically,

> Relator has direct and independent knowledge of the information on which the allegations are based because of her position with BMS/Sanofi, where she was trained as a sales representative to mislead doctors about Plavix. The scheme involved BMS/Sanofi mischaracterizing clinical studies and instructing their sales force to confuse physicians and promote a false narrative about Plavix's efficacy. Relator's direct and independent knowledge of the deceptiveness of BMS/Sanofi's marketing strategy results from the discrepancies between her sales training about Plavix and her instructions on its promotion. For example, she received the CAPRIE Road Map for training purposes, which revealed Plavix's non-significant efficacy data, and yet was instructed by BMS/Sanofi to promote Plavix in direct contradiction to its results.[81]

Thus, Relator is an "original source" of the allegations in the TAC because she was personally involved in the scheme.

Relator was an eyewitness and participated in Defendants' scheme to defraud the government, and her claims arise from her personal observations and involvement with the scheme. Accordingly, Relator's lawsuit is exactly what the *qui tam* provisions encourage. *See Atkinson*, 473 F.3d at 520 ("The FCA seeks to encourage persons with *firsthand* knowledge of fraudulent misconduct, or those who are either *close observers* or *otherwise involved* in the fraudulent activity to come forward." (emphasis added) (internal quotation marks and citation omitted)).

[81] Dkt. No. 90 ¶ 110 (citing Dkt. No. 90-1 ¶¶ 18-19, 22, 29, 32, 33, 36, 37).

2. The "Critical Elements" Of Relator's Claim Were Not Publicly Disclosed.

To determine whether there has been "public disclosure" of the information, courts look to see whether "'the critical elements' of fraud" have been disclosed. *United States v. Sodexho, Inc.*, No. 03-6003, 2009 WL 579380, at *7-8 (E.D. Pa. Mar. 6, 2009). In other words, only if either the fraud or *both* the misrepresented facts and the true facts are disclosed has there been "public disclosure" such that the jurisdictional bar applies. *Id.* And importantly, an FCA claim is actionable only if a person (or entity) "knowingly presents or causes to be presented . . . [to] the United States government . . . a false or fraudulent claim for payment . . . ." *United States ex rel. Watson v. Conn. Gen. Life Ins. Co.*, 87 F. App'x. 257, 260 (3d Cir. 2004). None of Defendants' references, taken separately or together, disclose this "critical element."

At most, the resources cited by Defendants suggest that Defendants were negligent—not fraudulent—in their promotion of Plavix.[82] The *Hall* complaint, for

[82] Several of Defendants' cited references categorically do not even constitute public disclosures, at least for some of Relator's claims. For false claims governed by the pre-PPACA statute, the public disclosure bar can be triggered by allegations in "[1] a criminal, civil, or administrative hearing, [2] in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or [3] from the news media." 31 U.S.C. § 3730(e)(4)(A) (pre-PPACA). On its face, this language would appear to include Defendants' references. The post-PPACA statute, however, limits public disclosures to those (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or

example, only alleges that Defendants knew, "or if they had paid attention to the findings of their own studies, *should have known*, that Plavix was not more efficacious than aspirin."[83] As publicly disclosed, Defendants' promotion of Plavix may have been a mistake or perhaps the result of drug representatives acting outside Defendants' authority. But nothing in the *Hall* complaint confirms that Defendants acted fraudulently.

Similarly, the government reports and letters reveal nothing more than the well-known facts that the "CAPRIE trial does not provide substantial evidence to support the implication that Plavix has superior efficacy over aspirin" and that statements suggesting otherwise "are misleading."[84] And although some of the

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other Federal report, hearing, audit, or investigation; or (iii) from the news media." 31 U.S.C. § 3730(e)(4)(A) (post-PPACA). Thus, for claims governed by the post-PPACA statute, Defendants' primary reference—the *Hall* complaint—along with Defendants Exhibits H and I do not constitute public disclosures because they are not federal cases where the Government is a party.

[83] *See* Dkt. No. 94-2, Second Amended Complaint ¶ 14, *Hall v. Bristol-Meyers Squibb Co.*, No. 06-5203 (D.N.J. May 1, 2009); *see also id.* ¶ 68 ("The Defendants knew *or should have known* that consumers such as the Plaintiff would suffer injury or die as a result of the Defendants' failure to exercise reasonable and ordinary care." (emphasis added)). The *Hall* complaint only alleges claims for defective design, manufacturing defect, failure to warn, negligence, negligent misrepresentation, and violations of the Florida Unfair Deceptive Trade Practices Act. As such, the Hall plaintiffs had no need to plead that Defendants "had actual knowledge," "acted in deliberate ignorance," or "acted in reckless disregard" of the truth about Plavix—allegations that are the heart of a FCA claim. *See, e.g.*, *Hindo v. Univ. of Health Scis./The Chicago Med. Sch.*, 65 F.3d 608, 613 (7th Cir. 1995).

[84] *See, e.g.*, Div. of Drug Mktg. & Commc'ns, FDA, Untitled Letter, May 9, 2001, *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplance RegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeof

news articles hint at Defendants' general bad acts, they do not expose the particular plan and course of conduct at issue here (i.e., training and instructing employees and sales representatives to "confuse" and mislead doctors), and, therefore, do not trigger the public disclosure bar. This "very high level of generality is inappropriate" to establish public disclosure. *United States ex rel. Goldberg v. Rush Univ. Med. Ctr.*, 680 F.3d 933, 935 (7th Cir. 2012).

This is not a minor point. Innocent mistakes or negligence are not actionable under the FCA. *See Conn. Gen. Life Ins. Co.*, 87 F. App'x. at 260. "[I]n order to establish the requisite knowledge, a plaintiff must demonstrate that the alleged offender had actual knowledge that it submitted a false or fraudulent claim for payment, or acted in deliberate ignorance or reckless disregard of the truth or falsity of the claim for payment." *Id.* In contrast to all prior public disclosures, Relator's allegations alone expose this "critical element."

Relator exposed and revealed that, despite knowing the truth about Plavix's efficacy compared to aspirin, Defendants knowingly trained and instructed their sales representatives to "confuse" and mislead doctors into prescribing the drug even when it was unreasonable and unnecessary to do so. For example, "[a]s a member of the sales force, [Relator] was instructed to present the PRoFESS data in a manner designed to confuse physicians and make them believe that Aggrenox

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ViolationLetterstoPharmaceuticalCcompanies/UCM166467.pdf (last visited Nov. 12, 2013).

was inferior to Plavix,"[85] "to also state that 'it should not be concluded from the study that Aggrenox has similar efficacy and safety to Plavix in stroke patients,"[86] to "promote[] Plavix as being superior to aspirin in stroke patients,"[87] "to encourage physicians to switch patients from aspirin to Plavix if they suffered a stroke while taking aspirin,"[88] and "to focus sales calls on physicians and prescribers whose patients relied upon" Government Payors."[89] Further, "Sanofi *require[d]* that [the sales force] promote Plavix as comparably safe to aspirin based on the CAPRIE study even though the CAPRIE study compared Plavix to a more toxic dose of aspirin that is not regularly prescribed today."[90]

As these allegations show, this is not a case where Relator merely has provided additional evidence of a previously disclosed fraud. The fact is that Relator is the first person to inform the government that Defendants affirmatively defrauded the government, knew the truth about Plavix, disregarded that truth, and devised a plan to use its employees and sales force to dupe doctors into prescribing Plavix and P&T Committees into including Plavix on their formularies—even after the FDA advised them to stop wrongfully promoting Plavix. Without these critical elements—the elements that expose and detail Defendants' fraudulent course of

[85] Dkt. No. 90-1 ¶ 29; *see also* Dkt. No. 90 ¶ 21.
[86] Dkt. No. 90-1 ¶ 29; *see also* Dkt. No. 90 ¶ 21.
[87] Dkt. No. 90-1 ¶ 18; *see also* Dkt. No. 90 ¶ 20.
[88] Dkt. No. 90-1 ¶ 19; *see also* Dkt. No. 90 ¶ 20.
[89] Dkt. No. 90-1 ¶ 32; *see also* Dkt. No. 90 ¶ 22.
[90] Dkt. No. 90-1 ¶ 22 (emphasis added); *see also* Dkt. No. 90 ¶ 20.

conduct—there is no claim under the FCA. *See Connecticut Gen. Life Ins. Co.*, 87 F. App'x at 260 ("[A] plaintiff must demonstrate that the alleged offender had actual knowledge that it submitted a false or fraudulent claim for payment . . . .").

3. Relator's Allegations Are Not "Based Upon" Or "Substantially The Same As" Public Disclosures.

If the Court finds that Relator was not an original source (which she is) and that the skeleton allegations of Defendants' general wrongdoing constitute public disclosure (which they do not), the Court should then ask whether Relator's action is "based upon" or "substantially similar to"[91] those public disclosures. *See U.S. ex rel. Atkinson v. PA. Shipbuilding Co.*, 473 F.3d 506, 519 (3d Cir. 2007). "Substantial similarity exists where there is 'substantial identity' between the publicly disclosed allegations and the allegations in the relator's complaint." *U.S. ex rel. Feldstein v. Organon, Inc.*, 364 F. App'x 738, 741 (3d Cir. 2010). The Third Circuit has found a *qui tam* action to be "based upon" a disclosure if the disclosure sets out either the *allegations* advanced in the *qui tam* action or *all of the essential elements* of the *qui tam* action's claims. *U.S. ex rel. Paranich v.*

[91] Prior to PPACA, the public disclosure bar applied to claims "*based upon* the public disclosure of allegations or transactions" in certain public sources. 31 U.S.C. § 3730(e)(4)(A) (pre-PPACA) (emphasis added). After PPACA, the bar was amended to apply "if *substantially the same* allegations or transactions as alleged in the action were publicly disclosed." 31 U.S.C. § 3730(e)(4)(A) (post-PPACA) (emphasis added).

Sorgnard, 396 F.3d 326, 335 (3d Cir. 2005) (emphasis added). Relator's allegations are nothing of the sort.

Relator's eyewitness accounts provide far more than the general notion of misconduct that can be gleaned from public sources. Relator factually describes, firsthand, Defendants' course of conduct to profit at government expense by "confusing" and misleading doctors to prescribe Plavix when it was unreasonable and unnecessary to do so.[92] There is no "substantial identity" between the publicly disclosed generalizations and relator's specific allegations. *See Feldstein*, 364 F. App'x at 741 (finding substantial similarity exists where there is "substantial identity" between the publicly disclosed allegations and the allegations in the relator's complaint). Accordingly Relator's claims fall outside the public disclosure bar.

D. RELATOR'S CLAIMS ARE TIMELY.

Under 31 U.S.C. § 3731(b), FCA claims may not be brought more than six years after the date of the violation ***or*** more than three years after the date when facts material to the right of action are known by the United States, "***whichever occurs last.***"[93] (emphasis added). "[T]he extension of the statute of limitations for

[92] *See, e.g.*, Dkt. No. 90 ¶¶ 3, 19-21, 23, 122-24; Dkt. No. 90-1 ¶¶ 18-19, 22, 29, 33, 36, 37.

[93] The majority of the state statutes track this same language. *See* California False Claims Act, Cal. Gov't Code § 12654; Chicago False Claims Act, Municipal Code of Chicago § 1-22-040(b); Colorado Medicaid False Claims Act, Colo. Rev.

discovery of the fraud is applicable to a relator as well as the government." *United States ex rel. Repko v. Guthrie Clinic, P.C.*, 557 F. Supp. 2d 522, 530-31 (M.D. Pa. 2008). There is no indication on the face of the complaint that the Government should have known about the fraud more than three years before this action was brought. Because Defendants' statute of limitations argument is an affirmative defense, it must be apparent from the face of the complaint that the statute of limitations has run in order to resolve the issue on a motion to dismiss, instead of in an answer or another procedural mechanism. *Robinson v. Johnson*, 313 F.3d 128, 135 (3d Cir. 2002). "If the bar is not apparent on the face of the complaint, then it may not afford the basis for a dismissal of the complaint under Rule 12(b)(6)." *Id.*

Stat. § 25.5-4-307(1); Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301l; Delaware False Claims and Reporting Act, Del. Code. tit. 6 § 1209(a)(1); District of Columbia Procurement Reform Amendment Act, D.C. Code 2-308.17(a); Florida False Claims Act, Fla. Stat. Ann. § 68.089(1); Georgia False Medicaid Claims Act, Ga. Code § 49-4-168.5; Hawaii False Claims Act, Haw. Rev. Stat. § 661-24; Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. 175/5(b)(1); Indiana False Claims and Whistleblower Protection Act, Ind. Code. § 5-11-5.5-9(b)(1); Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5K; Michigan Medicaid False Claim Act, Mich. Comp. Laws § 400.614(1)(a); Minnesota False Claims Act, Minn. Stat. Ann. § 15C.11(a); Montana False Claims Act, Mont. Code Ann. § 17-8-404(1)(a); New Jersey False Claims Act, N.J. Stat. § 2A:32C-11a; Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.170(1); North Carolina False Claims Act, N.C. Gen. Stat. § 1-615(a); Oklahoma Medicaid False Claims Act, Okla. Stat. Ann. § 63-5053.6(B)(1); Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-5(b)(1); Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-184(b); Virginia Fraud Against Taxpayers Act, Va. Code § 8.01-216.9. For the other states, Relator alleging a timeframe for the fraud prevents dismissal at this stage of the litigation.

Moreover, in the context of an FCA claim, "providing a range of time during which the events giving rise to the claim occurred is sufficient to withstand a motion to dismiss." *Dale v. Abeshaus*, 06-CV-04747, 2013 WL 5379384, at *13 (E.D. Pa. Sept. 26, 2013). Here, Relator alleges a time frame for her claims, which is appropriate. As such, "it is not apparent from the face of [the] complaint that the statute of limitations provides a basis for dismissal." *See id*. ("Here, plaintiffs allege that defendants submitted false claims between 2001 and 2008. Therefore, even if I were to accept defendants' assertion that plaintiffs may not recover for conduct which occurred prior to May 20, 2004, it is not apparent from the face of plaintiffs' complaint that the statute of limitations provides a basis for dismissal."). Defendants' request to limit the complaint to conduct occurring after March 30, 2005 should be denied.

E. RELATOR'S STATE LAW CLAIMS ARE APPROPRIATELY BEFORE THIS COURT.

Defendants' conclusory statements in Section V of its motion should not be considered by this Court because they are too vague to meaningfully address. To the extent that Defendants argue that the state law claims fail on the same basis as the arguments for the federal claims, Defendants' motion should be denied for the same reasons as it should be for the federal claims.

Defendants summarily state that Relator failed to comply with the *qui tam* provisions of the state false claims acts because such is not stated in the TAC. But

Defendants have not pointed to any requirements that Relator must *plead* compliance (versus actually comply). Each state *qui tam* provision carries with it a host of requirements for filing a claim. Defendants' argument suggests that in order to sufficiently plead her action, Relator must walk the Court through every procedural requirement under every state scheme and allege that it has complied with each. Such a requirement simply does not exist.

Defendants then argue that certain states only allow a *qui tam* to be brought in the state's own court, barring Relator from bringing these actions in federal court.[94] A sister district court has squarely rejected Defendants' argument, holding that regardless of state provisions dictating where to file a *qui tam*, federal courts have supplemental jurisdiction over state *qui tams* based on both 28 U.S.C. § 1367 and 31 U.S.C. §3732(b). *See United States ex rel Galmines v. Novartis Pharm. Corp.*, No. 06-3213, 2013 WL 5924962, at *3 (E.D. Pa. Nov. 5, 2013). In so holding, the court relied on the long-established principle that where state legislation governs, but federal jurisdiction exists, federal jurisdiction "is not subject to State limitation." *Id.* at *4 (quoting *Railway Co. v. Whitton's Admin.*, 80 U.S. 270 (1872)).[95]

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[94] Defendant cites to legislation in California, Connecticut, District of Columbia, Delaware, Florida, Georgia, Indiana, Massachusetts, and North Carolina that merely governs where to file a *qui tam* action in state court.

[95] Multiple circuit courts have recently affirmed this principle in various contexts. *See BNSF Railway v. O'Dea*, 572 F.3d 785 (9th Cir. 2009) ("A state

Defendants finally assert that certain state FCA statutes do not apply retroactively, but again offer no support for this proposition. For example, Defendants list New York, but courts in New York would not bar this case on that basis. *See Hogan v. Cuomo*, 67 A.D.3d 1144, 1145 (N.Y. App. 2009) ("Petitioner contends that the False Claims Act is inapplicable because it was enacted after petitioner began receiving pension benefits, it may not be applied retroactively and the statute of limitations has run. As petitioner's continuing receipt of benefits could constitute a continuing fraud, the False Claims Act may apply and the statute of limitations may not have run."). Similarly, Defendants merely request dismissal "where applying laws retroactively would violate the *ex post facto* clause of the United States Constitution," but give no basis for which claims or which state statutes they believe violate these. Relator alleges a continuous scheme of fraud spanning over a decade. Dismissal at this stage on the basis of state statutes' retroactivity or *ex post facto* arguments would be inappropriate.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion should be denied.

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cannot confer rights upon private parties and require that litigation between those parties must be confined to the courts of the state itself."); *Superior Beverage Co. v. Schieffelin & Co.*, 448 F.3d 910, 917 (6th Cir. 2006) ("[A] state may not deprive a federal court of jurisdiction merely by declaring in a statute that it holds exclusive jurisdiction."); *see also Allstate Ins. Co. v. Gammon*, 838 F.2d 73, 77 n.7 (3d Cir. 1988) ("We are aware that this statute if it were interpreted to deny parties access to the United States District Court without their consent, might well run afoul of the Supremacy Clause, U.S. CONST. art. VI, cl. 2.").

Dated: November 18, 2013.

Respectfully submitted,

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